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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,409	10/13/2004	Xia Xu	4239-64801-02	9192
45160 7590 02/27/2009 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER MOSS, KERI A	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 02/27/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,409	Applicant(s) XU ET AL.	
	Examiner KERI A. MOSS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 19-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 19-51 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 2, 2008. The Examiner thanks the Applicants for noticing that claims 49-51 were accidentally forgotten. The Applicant correctly identified claims 49-51 as fitting within Group IV.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims **1-9 and 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Visser et al. (High-performance liquid chromatography of the neuroactive steroids alphaxalone and pregnanolone in plasma using dansyl hydrazine as fluorescent label: application to a pharmacokinetic-pharmacodynamic study in rats, J Chrom B, vol. 745, pgs. 357-363 (2000)) in view of Bailey et al. (USP 5,807,748). Visser et al. teaches reacting a sample with a sulfonylhydrazide to form a sulfonylhydrazone of a ketosteroid (Fig. 1) and analyzing the reacted sample by high-performance liquid chromatography (abstract), wherein detection of the sulfonylhydrazone indicates presence of the ketosteroid (Section 3.). The non-polar stationary phase is a C18 stationary phase (Section 2.). A methanol/water solvent is used during the HPLC (Section 2.).

Visser et al. does not expressly teach analyzing the reacted sample by mass spectrometry. Bailey et al. teach using reversed-phase HPLC and electrospray mass spectrometry for separating and identifying a fluorescent derivative of an analyte molecule (Columns 1-4; Examples). Bailey et al. teaches that the disclosed method improves sensitivity (column 4). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Visser et al. with the separation and

identification techniques of Bailey et al. in order to gain the advantages of improved detection sensitivity.

6. Claims **1-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berliner (USP 5,272,134) in view of Bailey et al (USP 5,807,748). Berliner teaches reacting a sample with a sulfonhydrazide to form a sulfonhydrazone of a ketosteroid in the sample and analyzing the reacted sample (Examples 13-15). Berliner teaches us that using methanol washes the product clean (Examples 13-15) and teaches using a methanol/water elution ratio of 80:20 (Examples 13-15).

Berliner does not expressly teach the method of analysis used. Bailey et al. teach using reversed-phase HPLC and electrospray mass spectrometry for separating and identifying a fluorescent derivative of an analyte molecule (Columns 1-4; Examples). Bailey et al. teaches that the disclosed method improves sensitivity (column 4). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Visser et al. with the separation and identification techniques of Bailey et al. in order to gain the advantages of improved detection sensitivity.

7. Claims **16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over either Visser et al. in view of Bailey et al. or Berliner in view of Bailey et al. as applied to claim 1, supra, and further in view of Takadate et al. (A Convenient Derivatization with Anion Exchange Resin Catalysts for High-Performance Liquid Chromatographic Analysis. I. Derivatization of Estrogens with Dansyl Chloride, Chem. Pharm. Bull., vol.

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33, no. 11, pages 5092-5095 (1985)) in view of Findeis et al. (USP 5,854,204). See Visser et al. in view of Bailey et al, supra, or Berliner in view of Bailey et al., supra, which do not expressly teach using a sulfonyl halide following using the sulfonylhydrazide. Takadate et al. teach that derivatization of ketosteroid estrogens using a sulfonyl halide is an alternative derivatization to that of ketosteroids using sulfonylhydrazides. It would have been obvious to one of ordinary skill in the analytical chemistry arts to follow the derivatization of ketosteroids using sulfonylhydrazides with an alternative and well-known method of derivatization of ketosteroids using sulfonyl halide. The purpose or advantage of doing so would be to check the relative accuracy of the first method. Thus it would have been obvious for one of ordinary skill in the art to follow the sulfonylhydrazide reaction with a sulfonyl halide reaction to gain the advantages of comparison testing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797